

REMARKS

In the Office Action mailed from the United States Patent and Trademark Office on July 17, 2007, claim 1 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998) and further in view of Gagnon (1997); and claims 1, 4-12 and 24-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998), in view of Gagnon (1997), in view of Brock et al. (1991), in view of Nahir (EP 0 555 573 A1) and in view of Elliot (US 1,885,410). For the reasons set forth below, Applicant submits that the prior art fails to teach or suggest all the claim limitations. Thus, Applicant's claims are not obvious in view of the prior art references.

Applicant submits that the cited references do not teach every aspect of the claimed invention, as amended. Independent claim 1 recites a method for processing and administering an improved *Morinda citrifolia* product with increased capacity to scavenge lipid hydroperoxides and superoxide anion free radicals within the body, said method comprising: harvesting the fruit from a *Morinda citrifolia* plant; allowing fruit to ripen for 0 to 14 days; preparing said harvested fruit for extraction of the juice therefrom, wherein said preparing comprises: placing the ripened fruit in plastic lined containers, and holding the fruit in said containers for 0 to 30 days extracting the juice from said prepared fruit to obtain said *Morinda citrifolia* fruit juice, wherein said extraction comprises: mechanically separating seeds and peel from juice and pulp; filtering by centrifuge decanter with a screen filter size between 1 and 2000 microns, wherein said operating filter pressure may range from about 0.1 psig to 1000 psig combining said processed *Morinda citrifolia* product with other ingredients said dietary supplement comprising: a first juice from *Morinda citrifolia* fruit present in an amount between about 10 and 99.99 percent by weight;

processed *Morinda citrifolia* pulp; blueberry juice concentrate; grape juice concentrate; natural flavoring; consuming said dietary supplement; and inhibiting lipid peroxidation.

The method of making the product, and the various constitutive elements added to the product before delivery have a significant effect on lipidperoxidation inhibition. The amended claims more distinctly outline the importance of the harvesting and processing steps in order to produce an improved *Morinda citrifolia* product, which has increased and unexpected capacity to inhibit Lipidperoxidation.

The importance of the manufacturing steps utilized to process *Morinda citrifolia* products is confirmed in various published articles and by research performed by Applicant. Attached, please find a copy of “Drug Development; The Pain Killer Tree: An Ancient Remedy Rediscovered” (hereinafter “Drug Development”). The article, particularly the fifth paragraph, clearly conveys the unexpected results achieved when different processing steps are utilized. Freeze drying alone improved the efficiency of the noni product 267% over the closest other dried noni product. Congruent with the disclosure found in “Drug Development,” Chye discloses the concern that certain methods of manufacturing produce greater quality products, and that a Mr. Story and Wadsworth developed methods of harvesting, processing and bottling the juice that did not sacrifice the important effects natural ingredients. Also enclosed, please find an excerpt from U.S. Provisional Patent Application No. 60/251,417, to which the present application claims priority, detailing studies that substantiate the improved and unexpected efficacy produced when the claimed processing steps were utilized.

Chye, Schechter and Gagnon fail to teach or fairly suggest the particular processing steps that produce a *Morinda citrifolia* product developed particularly to scavenge lipid hydroperoxides. Chye provides a non-enabling disclosure, which indicates merely that “noni-

juice is the new darling of health-conscious Malaysians". Chye indicates that there have been no proper trials conducted with humans for verifying the efficacy of noni. Chye continues, indicating that various noni products are likely to hit the market, "[t]his naturally leads to the question: which form is the best to take? Other nagging questions arise, which juice is of the best quality? Which manufacturer guarantees quality control in the harvesting of the fruit and the bottling of the juice?"

Chye acknowledges that some noni products may be more effective than others, and that some products may be dangerous to human health. But Chye fails to provide guidance for overcoming this problem. Rather, "after three years, during which time they were oblivious to Dr. Heinecke's own research on noni, they [Stephen Story and John Wadsworth] developed a way to harvest, process and bottle the juice without sacrificing the important natural ingredients. They also developed a way to neutralise its pungent odour and horrible taste by adding grape juice and blueberry juice." Accordingly, Chye suggests that it is difficult to produce a noni product while maintaining the efficacy during processing and indicates that at the time of publication no assay had been performed to verify efficacy of any noni product, and that nagging questions remained (e.g. which processes would allow production of a noni product without sacrificing important natural qualities).

Chye does not place into the public knowledge a process for processing the noni plant which preserves the natural efficacy of the plant during processing. But rather, indicates that Steven Story and John Wadsworth had developed and maintained a secret a process. Chye places the world in possession of the fact that a secret process exists, not in possession of the process for producing the product itself. Accordingly, Chye fails to teach or fairly suggest the process steps recited in the claims of the present invention.

Schechter indicates that noni fruit contains vitamin C, selenium, and other substances that counteract inflammation and absorb free radicals in the body. However, Schetheter does not disclose processing steps claimed herein that produce the surprising scavenging properties claimed in the present invention. The composition as recited in the claims of the present invention has a scavenging affect which exceeds the regular intake of vitamin C and other known antioxidants. Experiments conducted in support of the present application indicated that the regular intake of the product of the present invention provides a stronger scavenging effect on superoxides and free radicals within the body than the regular intake of vitamin C, pycocogenol (Maritime pine bar extract), or grape seed powder. Specification, page 16, lines 6-15. While Schechter indicates that noni fruit has antioxidants, Schechter does not describe a method of processing and administering the noni fruit so as to provide an unexpected scavenging effect as recited in the present invention.

As the cited references fail to disclose or suggest all of the claim limitations of independent claims of the present invention, and further fail to suggest modifying the reference as suggested by the Examiner, the present invention is not obvious in view of such references.

For at least this reason, Applicant respectfully submits that the prior art does not explicitly or impliedly teach every aspect of the invention as claimed in the independent base claims. In addition, the dependent claims place further limitations on otherwise allowable subject matter. Accordingly, Applicant respectfully submits that the cited art does not teach every aspect of the claims as provided herein, and therefore does not render the claims obvious.

CONCLUSION

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

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